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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/758,003
Filing Date: January 09, 2001
Appellant(s): BAICHWAL ET AL.

Richard Aron Osman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 17 May 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences that will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The Appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The Appellant's statement in the brief that certain claims do not stand or fall together is not agreed with for the following reasons: Claims 1, 5, and 6 stand or fall with claim 3 because they are drawn to the same genus of polynucleotides encoding threonine 514, as specified in

claims 1, 5, and 6. Nucleotides 1540-1542, specified in claim 3, encode this amino acid. Thus the required structural feature is the same. Claims 1, 5, and 6 require that the encoded polypeptide be antigenically distinct from a polypeptide without the mutation at 314 and claim 3 requires that the polynucleotide not hybridize with polynucleotides without the mutation. These limitations do not distinguish the groups, each from the other, because they are consequences of the same structural feature, the mutation at nucleotides at positions 1540-1542 of the nucleic acid that encodes the mutation at position 514 of the polypeptide.

Claims 10-27 and 34 are drawn to sequences comprising particular regions around the mutation, and claims 29-33 are drawn to sequences comprising longer, but unspecified, sequences than those of claims 1, 3, 5, and 6. Claims 10-27 and 29-34 differ, each group from the other, by a requirement for antigenic distinction or for selective hybridization. As stated above, these limitations do not distinguish the groups because they are a consequence of the same structural feature. They impart no additional characteristics. The particular sequences claims in claims 10-27 and 34 do not serve to distinguish them from the broader generic claims 1, 3, 5, and 6 because there are no structural or functional characteristics associated with the different regions that distinguishes these claims from the broader ones. Similarly, the longer regions claimed in claims 29-33 do not differentiate them from sequences encompassing shorter regions because they do not result in any particular distinguishing characteristics. The issues involved in all of the claims are the same.

Thus, all claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3, 5, 6, 10-27, and 29-34 rejected under 35 U.S.C. 112, first paragraph, as lacking written description. This rejection is set forth in prior Office Actions, mailed on 3 June 200, 5 November 2003, and on 17 February 2004, and is summarized below.

The claims are drawn to polynucleotides that comprise only small regions of the disclosed sequence, and thus can vary substantially in length and in composition. The single required common feature among all of the claimed polynucleotides is that they encode a mutation at position 514 of the encoded polypeptide. This single amino acid is not sufficient to impart characteristic physical, structural, or functional features to the invention. While the dependent claims 10-27 and 34 are drawn to sequences comprising particular regions surrounding this mutation, there are no particular structural or functional characteristics ascribed to any of these regions; they merely surround the single mutation. Thus none of the particular regions has any features that would be characteristic of a genus other than this single mutation. Claims 29-33 encompass larger regions but, similarly, the specification does not attribute any defining characteristics to the regions encompassed. The limitations of antigenic distinctiveness or the ability to hybridize to one sequence but not the other is not sufficient to evidence possession of a genus of related molecules. There is no function associated with such limitations and they impart no structural features to the encompassed molecules. All that is required by these limitations is that they differ from sequences encoding the parent, serine-containing

molecule or hybridize to the threonine-containing sequence, not that they have any characteristics in common among themselves other than the single feature, encoding the threonine mutation at position 514, that is already required. Thus the claimed subject matter has not been described so as to reasonable convey to one skilled in the art that the inventors had possession of the claimed invention.

Claims 1, 3, 5, 6, 10-27, and 29-34 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO: 1 and for polynucleotides encoding SEQ ID NO: 2, does not reasonable provide enablement for sequences comprising only fragments of the disclosed sequence. This rejection is set forth in prior Office Actions, mailed on 3 June 2003, 5 November 2003, and on 17 February 2004, and is summarized below.

As is stated above, the claims are drawn to sequences comprising only small regions of the disclosed sequence. Thus they are broad because they encompass polynucleotides that are very different from the disclosed sequence. Any given embodiment need have only part of its sequence in common with the disclosed sequence, and the only feature that all embodiments of the invention are required to posses is a mutation encoding a single amino acid. The specification discloses that the polypeptide of SEQ ID NO: 2, which is encoded by the polynucleotide of SEQ ID NO: 1, is a kinase and binds molecules important in the transduction of TNF-related signals. However, the specification does not provide guidance for using any polynucleotides that do not have this function, but are encompassed by the claims. There is no function associated with sequences merely encoding a threonine residue set forth in the specification. The prior art does not provide compensatory teachings as to how one use such

molecules; the related proteins known in the art have similar functions to that of SEQ ID NO: 2 and thus provide no guidance as to how one of skill might use molecules that did not have such functions.

For these reasons, which include the lack of knowledge about functions of encompassed polynucleotides encoding polypeptides structurally related to SEQ ID NO: 2 that do not have the same function, the one working example of SEQ ID NO: 2, the lack of direction or guidance for using polynucleotides comprising only small regions of SEQ ID NO: 1, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

(11) Response to Argument

With respect to the rejection of the claims as lacking written description, Appellant argues that the subject matter is disclosed in the specification and Appellant is unable to discern any contrary allegation. Appellant argues that the claims are all restricted to probes or reagents for making them. Appellant additionally argues with respect to claims 1, 5, and 6 that the required region is not only one amino acid but is one of ten decapeptides. Appellant additionally argues that the encoded molecules are functionally limited to those antigenically distinguishable from the serine-containing polypeptide. With respect to claim 3 and depending claims, Appellant argues that the claims are limited to sequences comprising at least 24 nucleotides and thus that the common region is one of 22 polynucleotides. Appellant additionally argues that the polynucleotides are functionally limited to those that do not hybridize with the serine-encoding sequence. With respect to claims 10-27 and 29-34, Appellant argues that the claimed truncations are defined in the specification.

Appellant's arguments have been fully considered but have not been found to be persuasive.

Statements that the subject matter is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention are found on p. 2 of the office action of 3 June 2003, p. 2 of the office action of 5 November 2003, and p. 2 of the office action of 17 February 2004. The full text of the statement was not repeated in the actions of 5 November 2003 or 17 February 2004 but a statement that this text can be found in a prior action is included in the first paragraph of each of those actions.

As was stated with respect to the enablement rejection in the office action of 5 November 2003 (p. 4) and of 17 February 2004, the claims are not limited to probes or reagents for making them. They encompass far more than fragments of the disclosed sequence; there is no upper size limit and no limit as to the nature of the sequences other than that they contain the required fragment.

While Appellant asserts that the required common region for claims 1, 5, and 6 is one of ten decapeptides, as was stated on p. 3 of the office action of 5 November 2004 and on p. 3 of the office action of 17 February 2004, the only common feature among these decapeptides, and thus the only common feature required by the claims, is a sequence encoding a single amino acid. The claims require that any particular polynucleotide encode ten residues of SEQ ID NO: 2, but two polynucleotides meeting the limitations of the claims need not encode the same ten residues and need have only the sequence of three nucleotides required to encode a threonine in common. Thus the claims encompass polynucleotides that encode polypeptides that have only one amino acid in common. Furthermore, the required region of ten amino acids is a small fragment of the

encoded polypeptide and the specification does not teach that any of these decapeptides contain any structural features other than the single mutation that might serve to identify a genus of molecules with related characteristics. What is taught on p. 3 is that they are immunologically distinguishable from the serine-containing polypeptide but apparently are able to interact with the threonine mutant. While the individual fragments might therefore be useful in differentiating the serine molecule from the threonine molecule, what is claimed is a genus of molecules comprising these fragments. Antigenic distinction does, not, as stated above and in the previous office actions, define a genus of molecules with common properties. Furthermore, the limitation in the claims is a negative limitation that only requires that the encoded molecules be antigenically distinct from the serine variant and does not define anything they have in common with each other, only how they differ from another molecule.

Appellant asserts that the required common region for claims 3 and depending claims is one of 24 polynucleotides, but, similar to what was stated for claims 1, 5, and 6 above, while each sequence may have a region in common with that of SEQ ID NO: 1, two polynucleotides meeting the limitations of the claims need have only the three nucleotides encoding a threonine residue in common. Additionally, as was similarly stated above, the required region of 22 nucleic acids is a small portion of the disclosed sequence and the specification does not teach that any of these 22-mers are responsible for any characteristics that would define a genus. Fragments that hybridize to SEQ ID NO: 1 but not to the serine-encoding sequence, as is disclosed on p. 4, might, like fragments that encode antigenically distinct peptides, be useful. However, this characteristic does not, as was stated above and in previous office actions, impart any common function to molecules comprising these fragments, nor does it define any particular

structural features. Furthermore, no hybridization conditions are required and thus no particular group of molecules is encompassed by the claims, since hybridization is highly dependent on the conditions employed.

Appellant argues with respect to claims 10-27 and 29-34 that the claimed truncations are described in the specification. However, the claims use the open language of "comprising", as do all of the other claims. Thus they encompass all sequences containing the truncation and meeting the requirement of either antigenic distinctiveness or selective hybridization. This genus of molecules is what is not described in the specification so that the artisan would understand that the inventors were in possession of it.

Claims 29-33, which require a greater region of identity to SEQ ID NO: 1 than the broader generic claims, nonetheless require only regions that are a small portion of SEQ ID NO: 1, which is 2016 nucleotides in length. As with the smaller fragments discussed above, the specification does not teach that any of the regions encompassed by these claims are responsible for any particular characteristics that would describe a genus of related molecules comprising these regions.

With respect to the rejection of the claims as lacking enablement commensurate in scope with the claims, Appellant argues that the sequence listing rules permit the description of the molecules with reference to a single inclusive sequence. Appellant additionally argues that claims 1, 5, and 6, encompass only ten possible decapeptides. Appellant argues that the claims are functionally limited to polynucleotides encoding polypeptides immunologically distinguishable from the serine-containing molecule. With regard to claim 3 and its

dependencies, Appellant argues that there are only 22 possible 24-mers that include the mutation and that the claims are functionally limited by the hybridization requirements. Appellant argues that determining whether a given polynucleotide meets the limitation of the claims requires the determination of whether any of the possible sequences are present and then using routine screening to determine if the requisite function was met. Appellant argues that no inoperable embodiments are encompassed. Appellant additionally argues that the experimentation required is less than that permitted under *Wands*. Appellant argues that the specification provides sufficient teaching to enable one of ordinary skill in the art to practice the claimed invention. Appellant additionally argues that claims using "comprising" language have been found allowable by the Examiner. Appellant further argues that claims 10-27 and 29-34 are limited to molecules specifically exemplified.

Appellant's arguments have been fully considered but have not been found to be persuasive.

As was stated on p. 4 of the office action of 17 February 2004, no objection to the method in which Appellant has claimed the sequences has been made. With respect to Appellant's arguments that claims 1, 5, and 6 encompass only ten possible decapeptides, as was stated above, they encompass polynucleotides encoding sequences comprising one of ten possible decapeptides. Thus they are not limited in size. Furthermore, the full scope of the claims encompasses polynucleotides having in common only a sequence encoding a threonine residue. Also as was stated above, the requirement that the encoded polypeptides be distinguishable from the serine-containing version does not require that the encoded polypeptides have anything in common with each other. Furthermore, one of skill would not know how to use a protein or the

polynucleotide encoding it merely because it was antigenically distinct from another protein. Similarly, claim 3 and claims depending from it encompass molecules not limited in size and having in common with each other only a sequence of three nucleotides. Hybridization does not provide a functional limitation since it requires no particular features and since no hybridization conditions are specified.

Appellant argues that no inoperable embodiments are included and that the amount of experimentation required is less than that allowed in *Wands*. However, the instant claims encompass a genus of molecules that includes molecules comprising one of a number of small fragments. Inoperable elements are excluded only because the claims require that the molecule have the claimed hybridization or antigenic characteristics, not because of any structural features of the genus that exclude inoperative elements. Additional nucleotides, limited neither by number nor by any structure, are encompassed by the claims and could have a substantial and unpredictable effect on hybridizaton characteristics of the polynucleotides, and on the antigenicity of the encoded proteins. Absent any guidance as to which additional elements could be present and which could not, one of skill in the art would be unable to predict what molecules potentially within the scope of the claims would have the claimed characteristics. To screen potential members of such a large genus, whose members, as stated above, need have very few structural characteristics in common, without guidance as to which are likely to meet the limitations of the claims, would thus require undue experimentation, regardless of the simplicity of the screens.

Wands, as Appellant indicates, deals with monoclonal antibodies. As was stated in Wands, one of skill in the art could, and would routinely expect to, produce an antibody meeting

the limitations of the claims. However, the instant claims require not just one successful outcome of an experiment, as is described in *Wands*. They encompass an entire genus of molecules with insufficient structural information to allow the artisan to make and use them.

Appellant argues that claims using "comprising" language have been found allowable. These claims are drawn to polynucleotides comprising a sequence that encodes the entire RIP kinase mutant, which Appellant has shown to have kinase activity. Thus the essential features of the molecule are clearly present and the skilled artisan would know how to make and use it. Appellant argues that claims 10-27 and 29-34 are limited to embodiments exemplified in the specification. However, as stated above, all that is disclosed in the specification are the truncated sequences, not the characteristics of sequences comprising them that meet the limitations of the claims.

Thus, the claims are broadly drawn to encompass a large number of structurally distinct molecules, and, without further guidance, it would require undue experimentation for the skilled artisan to make and use the invention.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

JANET ANDRES
PRIMARY EXAMINER

Janet L. Andres, Ph.D
July 28, 2004

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